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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR part 417

[Docket No. FSIS-2009-0019]

HACCP Systems Validation

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of the final revision of the Compliance Guideline for Hazard Analysis Critical Control Point (HACCP) systems validation and responding to comments received on the draft guide that FSIS published in May 2013 in the Federal Register. In addition, FSIS is announcing its plans to verify that establishments meet all validation requirements.

DATES: Establishments may start using the new guidance now. FSIS will begin verifying that large establishments meet all validation requirements on January 4, 2016. FSIS will begin verifying that small and very small establishments meet all verification requirements on April

4, 2016.

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Background

FSIS administers the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) to protect the health and welfare of consumers by preventing the distribution in commerce of meat or poultry products that are unwholesome, adulterated, or misbranded. To reduce the risk of foodborne illness from meat or poultry products, FSIS issued regulations on July 25, 1996, that require that federally inspected establishments adopt HACCP systems (61 FR 38806). These regulations require that federally inspected establishments adopt measures to prevent or control the occurrence of food safety hazards at each stage of the production process where such hazards are reasonably

likely to occur.

The HACCP regulations in 9 CFR part 417 require that establishments validate the HACCP plan's adequacy to control the food safety hazards identified by the hazard analysis (9 CFR 417.4(a)). These regulations prescribe requirements for the initial validation of an establishment's HACCP plan and require that establishments "conduct activities designed to determine that the HACCP plan is functioning as intended." During this initial validation period, establishments are to "repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions" prescribed in their HACCP plans (9 CFR 417.4(a)(1)). Validation under 9 CFR 417.4(a)(1) requires that establishments assemble two types of data: 1) the scientific or technical support for the judgments made in designing the HACCP system, and 2) evidence derived from the HACCP plan in operation to demonstrate that the establishment is able to implement the critical operational parameters necessary to achieve the results documented in the scientific or technical support. The establishment is

to maintain the initial validation records for the life of the HACCP system to meet the requirements of 9 CFR 417.5(a)(1) and 9 CFR 417.5(a)(2).

The regulations also provide that "[v]alidation ... encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities" (9 CFR 417.4(a)(1)). Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). Thus, validation of the HACCP system involves validation of the critical control points in the HACCP plan, as well as of any interventions or processes used to support decisions in the hazard analysis.

History of Validation Guidance

In March 2010, FSIS posted on its web site an initial draft guidance document to assist the industry, particularly small and very small establishments, in complying with the requirements for HACCP systems, pursuant to 9 CFR 417.4.

On June 14, 2010, FSIS held a public meeting to discuss the initial draft HACCP validation guidance and received input from stakeholders. The transcript of the June 2010 public meeting is available on the FSIS Website at: [http://www.fsis.usda.gov/wps/wcm/connect/2708ef10-4996-4324-a2e2-3b6501ac81b1/Transcripts HACCP Validation 061410.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/2708ef10-4996-4324-a2e2-3b6501ac81b1/Transcripts_HACCP_Validation_061410.pdf?MOD=AJPERES).

FSIS received over 2,000 comments on the initial draft guidance, particularly with respect to the use of microbiological testing to validate the effectiveness of HACCP systems in controlling biological hazards. The Agency considered the issues raised by the comments received in response to the May 2010 Federal Register notice and at the June 2010 public meeting and developed an updated second draft of the compliance guidance.

On September 22-23, 2011, FSIS shared the second draft of the HACCP validation guidance with the National Advisory Committee on Meat and Poultry Inspection (NACMPI). NACMPI reviewed the draft and provided comments and suggestions to FSIS on how to improve the guidance. The NACMPI report is

available on the FSIS website at:

[http://www.fsis.usda.gov/wps/wcm/connect/c87523dc-44d4-446e-be03-a3e60b2f8e8f/Validation Issue Paper Final.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/c87523dc-44d4-446e-be03-a3e60b2f8e8f/Validation_Issue_Paper_Final.pdf?MOD=AJPERES).

The Agency made additional revisions to the draft guidance in response to the input from NACMPI.

In a May 9, 2012, Federal Register notice (77 FR 27135), FSIS announced the availability of, and requested comments on, the revised draft guidance document (<http://www.fsis.usda.gov/wps/wcm/connect/d000cb67-23bc-4303-8f7b-71dcba5e7cd7/2009-0019.pdf?MOD=AJPERES>). In the May 2012 Federal Register notice, the Agency also clarified its requirements for HACCP system validation and responded to the comments that it had received on the initial draft guidance. FSIS received fifty-one (51) comments on its May 2012 revised draft guidance.

FSIS carefully considered the comments and, in a May 2013 Federal Register notice (78 FR 32186; May 29, 2013), announced a further revised draft guidance document. In addition to responding to comments and publishing the newly revised draft, FSIS also announced a final public meeting,

which was held on June 25, 2013. The transcript of the June 2013 public meeting is available on the FSIS Website at: <http://www.fsis.usda.gov/wps/wcm/connect/d618094d-20f2-40a3-9103-a587b2fd8a01/Transcript-HACCP-Validation-062513.pdf?MOD=AJPERES>.

Final Guidance

The final guidance is posted at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index>. FSIS encourages establishments to use the guidance to assist them in complying with validation requirements. This guide represents FSIS's thinking and has been updated based on the most recent comments discussed below. FSIS will update it as necessary in the future.

In response to the comments discussed below, the Agency made several improvements to the final guidance to clarify scientific support and in-plant data requirements. In addition to adding a description of expert advice from a processing authority as an example of an acceptable type of scientific support, the guidance now also provides information on how to design challenge studies and on types

of microbiological data that should be included in the scientific support. FSIS has also included a new section in the guidance on the types of scientific support that could be used to validate prerequisite programs and a description of best practice guidelines that may be used as scientific or technical support. FSIS has provided additional information on how establishments should address situations where their scientific support does not include measurements of all critical operational parameters. The guidance also clarifies the type of in-plant data that establishments should collect to validate that a new technology addresses hazards as intended. In addition, FSIS has added information on how establishments should validate that a prerequisite program works across multiple points or steps in the process. Finally, the guidance now contains an additional example of scientific support and in-plant data that can be used to validate storage temperature prerequisite programs.

Response to Comments:

FSIS received twenty-one (21) comments on its May 2013 revised draft guidance on HACCP validation from small and

very small meat or poultry processors, trade associations, corporations, a consumer advocacy organization, a professional organization, and an individual. The following summarizes and responds to the major issues raised in the comments to the most recent draft guidance document.

1. Concerns about Validation, Its Applicability, and Cost

Comment: A few commenters questioned the need for, and purpose of, the HACCP validation guidance, and several others sought additional information about what FSIS hopes to achieve by publishing the guidance. One commenter requested that, on an ongoing basis, FSIS provide examples of inadequate validation.

Response: As addressed in response to comments in the May, 2013 Federal Register notice (78 FR 32186), the validation guidance is necessary because the Agency has found that establishments have not adequately validated their systems. For example, following a 2011 foodborne illness outbreak involving Lebanon bologna, FSIS found that the establishment's scientific support on file did not match the process the establishment was using to make the bologna. In 2012, FSIS concluded that E. coli (non-O157)

positives likely occurred because of improperly designed interventions. Similarly, FSIS determined that an outbreak involving chicken pot pies in 2007 and a 2011 outbreak from turkey burgers may have occurred because of improperly validated cooking instructions.

FSIS developed the guidelines particularly to help small and very small establishments comply with the regulatory requirements for validation. By periodically updating the guidance document, FSIS will continue to share, and explain how to address, examples of inadequate validation that are associated with food safety problems.

Comment: Many commenters stated that cost of validation is high. One commenter said that the cost of validation may discourage meat establishments from implementing new food safety strategies or interventions

Response: Validation requirements are not new. FSIS estimates that costs associated with any new validation activities will be minimal. As addressed previously in response to comments and in previous versions of the guidance, microbiological testing is only necessary for in-plant data in limited circumstances, and FSIS has provided low cost ways that establishments can validate their systems in place of microbiological testing. FSIS expects that many establishments will be able to gather the

necessary in-plant data from HACCP records already routinely being generated as part of the HACCP system.

Comment: A few commenters stated that FSIS is altering the meaning of "validation," especially when looking at accepted HACCP validation methods from 1996 to today. One commenter asked whether an establishment could choose "conventional" command and control inspection instead of meeting HACCP requirements, including validation requirements, if the establishment has a history of producing a safe product.

Response: The final version of the guidance document is consistent with the principles of validation as outlined in the 1996 Pathogen Reduction; Hazard Analysis and Critical Control Point Systems Final Rule (HACCP Final Rule). The HACCP Final Rule stated that data assembled to validate a HACCP plan are usually of two types: (1) theoretical principles, expert advice from processing authorities, scientific data, or other information demonstrating that particular process control measures can adequately address specified hazards (such as studies establishing the temperatures necessary to kill organisms of concern); and (2) in-plant observations, measurements, test results, or other information demonstrating that the control measures, as written into a HACCP plan, can be

implemented within a particular establishment to achieve the intended food safety objective. FSIS recognizes that there has been misunderstanding related to the principles of validation, which is why the Agency has developed this compliance guideline and will be issuing instructions to the field once establishments have been given the time to assemble the necessary documentation.

As explained in the May 2013 Federal Register notice, the HACCP Final Rule has resulted in great improvements in food safety. The Agency is not going back to a command and control inspection approach because it does not provide establishments with the flexibility to design innovative systems and puts the responsibility for ensuring food safety on FSIS as opposed to the establishment.

Comment: One commenter recommended that the guidance clarify that establishments need to validate that prerequisite programs work as intended in the overall HACCP system to prevent hazards from occurring. The commenter said that the guidance should discuss validation of prerequisite programs as a complete system, where those controls are intended to support a conclusion that a hazard is not reasonably likely to occur.

Response: Validation is the process of demonstrating that the HACCP system, as designed, can adequately control

identified hazards to produce a safe, unadulterated product. Prerequisite programs designed to support a decision in the hazard analysis are part of the HACCP system. When an establishment determines that a hazard is not reasonably likely to occur because the prerequisite program prevents the hazard, that prerequisite program becomes part of the HACCP system. Therefore, as the commenter recommended, establishments need to validate prerequisite programs designed to support decisions in the hazard analysis (e.g. Sanitation Standard Operating Procedures, purchase specifications, antimicrobial interventions) to ensure that the overall system can operate effectively. FSIS agrees that HACCP systems are generally designed to provide multiple hurdles of control. However, establishments should be able to support that each hurdle provides some level of prevention or control for the identified hazards.

As explained in the guidance, in order to validate such programs, establishments need to provide scientific documentation that supports that the programs will work as intended and to collect in-plant data to support that the programs can be implemented as designed. FSIS has revised the guidance to provide more examples related to validation of prerequisite programs.

Comment: Several commenters stated that some small establishments produce products so infrequently that they may not be able to obtain 13 production days' worth of records within 90 calendar days. One commenter said that FSIS should ensure that establishments are afforded sufficient flexibility to tailor their HACCP systems to their specific circumstances and questioned the need for a mandatory, fixed validation period. One commenter asked for additional instruction on the information to include with a request to the District Office for additional time to collect in-plant data (e.g., longer than 90 days). Another commenter requested clarification regarding whether the request for an extension to obtain records necessary for validation applies only to establishments under a conditional grant, or if it applies to all establishments.

Response: The regulations provide that the initial validation period is 90 calendar days (9 CFR 304.3(b) and (c) and 381.22(b) and (c)). Ninety days is the period whether a new establishment is operating under a conditional grant, or an existing establishment begins producing new product. Under either situation, for the first 90 days, establishments validate that their system is working as intended to address hazards. For large establishments, 90 calendar days equates to approximately

60 production days. (See FSIS Directive 5220.1 and 78 FR 32187.) FSIS recognizes that many small and very small establishments do not operate daily. Therefore, the guidance also states that a minimum level of records from 13 production days within those initial 90 calendar days should be used to initially validate a small or very small establishment's HACCP system. This number is consistent with FSIS Directive 5220.1 related to an establishment's initial validation. The Agency is recommending small and very small establishments review data from as few as 13 production days because it recognizes that collecting 60 production days' worth of records may be burdensome to small and very small plants.

If the establishment infrequently produces several products that are each part of a separate HACCP category, there is inherent risk with the processes if the establishment does not have experience in producing them. Therefore, to determine whether the system is properly designed and executed, even though the regulations provide 90 days for initial validation, an establishment needing more than 90 days can ask the District Office, in writing, for additional time to collect at least 13 production days of records when it first starts operating, when it begins producing new product, or for a modified HACCP plan if the

results of a reassessment indicate additional support is needed. In the request, an establishment should state why more than 90 days are needed to collect the in-plant validation data, and how it plans to gather at least 13 production days worth of in-plant validation data within the next 30 calendar days. The request will then be evaluated on a case by case basis. The establishment should consider focusing validation activities on the product produced most frequently within each HACCP category. In addition, the establishment may consider evaluating data collected for products across multiple HACCP categories to determine whether the data together can support its ability to meet critical operational parameters.

Small and very small establishments that do not currently have the necessary in-plant demonstration data will have until April 4, 2016 to collect the necessary documentation. Infrequent producers should be able to collect data from 13 production days over this time-frame.

Comment: One commenter questioned whether small plants receiving boxed beef components will be required to validate how their multiple processes will address contamination introduced to the product before arriving at the establishment.

Response: All establishments are required to validate that their food safety systems address hazards. There is no one, absolute way in which an establishment producing raw non-intact beef components is to control or prevent Shiga-toxin producing *Escherichia coli* (STEC) organisms in the product. An establishment may have Critical Control Points (CCPs) in its HACCP plan to control the hazard, may use its Sanitation Standard Operating Procedures or another prerequisite program to prevent the hazard, or may use a combination of these mechanisms. Establishments receiving product for grinding may have purchase specifications requiring that all their suppliers have one or more CCPs validated to eliminate or to reduce STEC organisms below detectable levels. Establishments, as part of their purchase specifications, may also receive certificates of analysis with each lot of raw beef components stating that the product has been tested and is negative for STEC organisms. In order to validate such pre-requisite programs, establishments need to provide scientific documentation that supports that the programs will work as intended and to collect in-plant data to support that the programs can be implemented as designed. In the guidance, the validation worksheets include an example of the types of scientific support and in-plant data that can be used to

validate a prerequisite supplier program that is designed to prevent the hazard from *E. coli* O157:H7 in raw ground beef or beef trim from being reasonably likely to occur.

In-plant Data

Comment: Two commenters stated that the Agency is trying to mandate testing through enforcing validation requirements.

Response: As addressed in the May, 2013 Federal Register notice (78 FR 32189) and previous drafts of the guidance, microbiological testing is needed for in-plant data in only limited circumstances where the scientific support is inadequate. FSIS will not require establishments to gather in-plant data before and after the application of an intervention if the establishment has adequate scientific supporting documentation, is following the parameters in the scientific support, and can demonstrate that it can meet the critical parameters during operation.

Scientific Support

Comment: One commenter stated that an establishment lacking experience with a new technology should not have to collect additional scientific support for its process and

should be able to rely on existing scientific support and in-plant data.

Response: The current version of the guidance clarifies that an establishment introducing a new technology not established in the literature or applying a standard technology in an unusual way (e.g., modifying critical operational parameters from the literature) should gather scientific support and in-plant validation for its new or modified HACCP system under commercial operating conditions. It also clarifies that an establishment that lacks experience with a new technology should also gather scientific and in-plant validation data with the exception of when the effectiveness of the new technology has already been studied, but the establishment lacks experience implementing the technology. In this case, the effort to develop such information may focus more on the collection on in-plant validation data.

Comment: Many commenters stated that there will always be differences between scientific studies and actual establishment processes, and that critical operational parameters implemented in actual processes may be missing from or different than those in the supporting scientific studies. Some commenters were also worried that it may be

costly to conduct the necessary scientific research on the specific process used in the establishment. One commenter also said that the fact that the guidance states that "equipment" is a critical operational parameter may lead some establishment personnel, as well as FSIS inspection personnel, to assume that the equipment must be exactly the same (e.g., same manufacturer or model number) as that used in the scientific study. Another commenter asked whether establishments are required to validate each piece of equipment. One commenter also requested the Agency define "process authority" and state when information from a processing authority would be acceptable scientific support.

Response: As explained in the current and previous versions of the guideline, critical operational parameters are the specific conditions that the intervention must operate under in order for it to be effective. Therefore, if the critical operational parameters implemented in the actual process are consistent with those in the supporting documentation, then establishments can expect to achieve similar results as those found in the scientific support. FSIS has identified a number of cases where differences in critical operational parameters between an establishment's scientific support and those implemented in the actual

process led to food safety problems. For this reason, it is important that the establishment's actual process follow the critical operational parameters in its scientific support.

FSIS recognizes that there may be cases where levels of a critical operational parameter in the scientific support may not match the level used in the actual process but is still effective. In those cases, as stated in the guidance, to document its scientific support the establishment should document its scientific rationale for determining that a different level would not affect the efficacy of the intervention or process. Such a justification can be provided by a process authority. However, as recommended in the guideline, the justification should include reference to peer-reviewed scientific data and should not rely on the processing authority's expert opinion alone to ensure that the decision is science based. If the establishment does not have a scientifically based rationale for why the different level would not affect the efficacy of the intervention or process, then the establishment would need to gather additional data.

When an establishment uses critical operational parameters from multiple studies together in the same process, the establishment will need to support that the

new combination of parameters would be as effective as those studied in the individual articles. An establishment will also need additional support if its documentation does not contain measurement of a critical operational parameter. For example, humidity is known to be a critical operational parameter during cooking. If an establishment's support for a heat treatment does not address humidity, the establishment will need to document why this parameter is not critical for that treatment. If no scientific justification can be provided, then the establishment will likely need additional data to support the undocumented process.

The guidance continues to state that equipment is a critical operational parameter because the correct equipment is necessary to achieve other critical operational parameters within the process. Based on the comments, FSIS has clarified in the revised guidance that the equipment is a critical operational parameter in situations when using completely different equipment (e.g., a manual spray pump vs. a spray cabinet or a commercial smokehouse vs. a home-style dehydrator) would not achieve the critical parameters of the study (such as temperature, pressure, duration, volume, relative humidity). In most cases, the same equipment produced under a different model

number or by a different manufacturer (e.g., a spray cabinet or smokehouse produced by a different manufacturer than that reported in the scientific support) should not affect the establishment's ability to meet other critical operational parameters such as temperature or pressure.

Comment: One commenter asked whether Agency personnel would accept many commonly used supporting documents (e.g. Appendix A of the Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products) as scientific support for validating the establishment's process.

Response: Establishments may continue to use Appendix A as scientific support to validate that their food safety system effectively addresses hazards. FSIS included a Q&A in the previous and current versions of the guidance that addresses this concern. Specifically, the guidance reads, "Question: If I use [Appendix A](#) as the scientific support documentation for a fully cooked RTE process, do I need additional scientific information? Answer: No, [Appendix A](#) has been validated to achieve the performance standards for the reduction of *Salmonella* contained in 9 CFR 318.17(a)(1) and 381.150(a)(1). Therefore, provided all critical operational parameters can be met, no additional support is needed." FSIS has and will continue to instruct inspection

program personnel (IPP) and Enforcement, Investigation, and Analysis Officers (EIAOs) that FSIS guidance documents are a type of scientific support that may be used by establishments to meet the first element of validation.

Comment: One commenter questioned how an establishment could relate the effectiveness of a food safety strategy to a specific pathogen and adhere to the process that actually occurs in the plant, if pathogens cannot be introduced into the establishment. The commenter references a 2002 guidance document titled "Guidance for Minimizing the Risk of *Escherichia coli* O157H:7 and *Salmonella* in Beef Slaughter Operations"

(<http://www.fsis.usda.gov/wps/wcm/connect/74de2bea-74d6-491b-b2cf-0047650bf0c6/BeefSlauterGuide.pdf?MOD=AJPERES>)

and a discussion in the guidance document regarding indicator testing. Another commenter stated that the following statement may prevent innovation when scientific support is not readily available: "[i]n general, establishments should not rely on scientific support containing data only from indicator or surrogate organisms unless there is sufficient data to establish a relationship between the presence or level of a pathogen or toxin and the indicator organism." The commenter said that indicator

or surrogate organisms can be used in-plant, provided there is data to establish a relationship between the two.

Response: The previous and current versions of the validation guidance document address the use of indicator organisms during in-plant validation studies (page 14). FSIS agrees that an establishment may use an indicator or surrogate organism to validate a process in-plant, provided there is data to establish a relationship between the indicator or surrogate and pathogen. This fact is stated on page 14 and is consistent with the discussion on indicator organisms in the "Guidance for Minimizing the Risk of *Escherichia coli* O157H:7 and *Salmonella* in Beef Slaughter Operations." FSIS does not agree that the guidance will prevent innovation and is unclear why the commenter feels it will prevent innovation.

Comment: Several commenters suggested that a consortium to identify critical operational parameters would be useful. Commenters also requested that FSIS provide a reference guide, pointing establishments to scientific documents and guidance on support for monitoring frequencies of CCPs be provided. One commenter asked where small and very small plant owners should get assistance with validating their HACCP plans and asked whether, and to

what extent, the Agency's small plant office will give guidance to plant operators.

Response: FSIS has several resources available to assist establishments with identifying critical operational parameters from scientific support documents including the askFSIS system and the small plant help desk. FSIS has also identified HACCP contacts and coordinators on its website that provide technical advice, assistance, and resources and that conduct activities to support HACCP implementation in small and very small plants.

Comment: Two commenters stated that the guidance that establishments validate at least one product per HACCP category was not helpful. One of the commenters said that the Agency is instructing the meat industry to conduct its own individualized risk assessment of the products produced and to make the appropriate determination without any guidance from the Agency. The other commenter predicted that Agency personnel will not accept in-plant data for one product within each HACCP category as sufficient to validate the food safety system.

Response: The guidance explains how to properly validate by identifying at least one product per HACCP category for which the establishment collects in-plant data. FSIS has provided food science principles that can

be used to identify the products using a risk-based framework. By using such principles establishments can select a product most representative of a worst case scenario and therefore collect in-plant data most protective of public health. FSIS recognized that collecting data for more than one product within each HACCP category could be burdensome. Therefore, the Agency requested input from NACMPI, and the committee agreed with this approach.

Comment: A few commenters requested that the Agency include examples of processes that may use Appendix A and Appendix B as scientific support for validating their food safety system, since these Agency documents are commonly utilized as scientific support.

Response: FSIS added examples of processes that can use Appendix A or B as scientific support in the May 2013 guidance. Examples are provided on pages 60 and 63 for processes using Appendix A and Appendix B as scientific support.

Examples

Comment: One commenter asked why the roast beef example in the validation worksheet (that used Appendix A as the scientific support) did not identify dwell time.

Response: The example using Appendix A on page 63 does include a dwell time of 112 minutes.

Comment: One commenter recommended that the worksheet examples be more specific in terms of the type of data that should be collected.

Response: The guidance provides additional examples of the types of scientific support and in-plant data that establishments could maintain for different products and processes in Appendix 4. As explained in the guidance, if an establishment has a specific question regarding the type of data that should be collected for its process and product, it can submit a question to the askFSIS system.

Comment: One commenter said that the ongoing verification activities that are listed in the example on page 33 are unreasonable. Based on a particular example, the commenter also expressed concern that FSIS will require establishments to monitor all parameters on an ongoing basis. One commenter recommended that FSIS explain that the critical operational parameters are related to initial validation, and that not all critical operational parameters need to be monitored on an ongoing basis.

Response: The current and previous versions of the guidance recognize that researchers may measure a number of parameters during a scientific study. However, not all of

these are critical to the efficacy of the intervention studied. The establishment should document and explain any differences in its production process relative to any of the studies it used as supporting documentation. The current and previous versions of the guideline also state that establishments may only need to verify whether some of the critical operational parameters are working as intended during the initial validation period (e.g., spatial configuration). The Agency does agree that in the cited example in the guidance it was unclear (ongoing verification activities on page 32), and FSIS has better delineated the activities that are conducted as part of monitoring vs. ongoing verification in the current guidance.

Agency Training and Implementation

Comment: Several commenters asked the Agency to identify who is going to train all of the FSIS inspectors. The commenters also said FSIS needs to ensure consistency in enforcing verification requirements. One commenter requested that FSIS issue formal instructions to field personnel on verifying that establishments meet validation requirements. The commenter also recommended that FSIS provide IPP with on-line training.

Response: FSIS will provide instructions to IPP and EIAOs on how to verify validation requirements through FSIS Notices and Directives. The Agency also plans to provide necessary training to IPP and EIAOs.

Comment: One commenter asked that Agency outreach staff conduct regional sessions around the country to explain validation requirements to industry.

Response: FSIS will be holding webinars with the industry to communicate the recommendations in the final guidance document, clarify the regulations, and explain how FSIS will verify that establishments use both scientific support and in-plant data to validate that their systems, as designed and implemented, are working to address hazards.

Comment: One commenter said that large establishments should be given more than six months to assemble the necessary in-plant validation documentation. The commenter stated that not all establishments may produce all products under all HACCP plans during the six-month period. Another commenter said that small and very small plants should be given more than 3 months longer than large plants to assemble the necessary documentation.

Response: FSIS will implement its new verification activities by phasing them in based on establishment size.

For large establishments, the Agency plans to wait until January 4, 2016, to start verifying that establishments meet all validation requirements, including maintaining in-plant validation data. Thus, large establishments will have approximately seven months to gather all necessary in-plant demonstration documents. FSIS believes this timeframe is adequate for large establishments to gather the necessary documentation because many of these establishments will be able to gather in-plant data from HACCP records that are already generated as part of the monitoring of critical limits or parameters of prerequisite programs. In addition, FSIS's implementation will correspond with establishments' annual reassessment. As part of the annual reassessment, establishments will review the data gathered during initial validation along with other documents gathered as part of the implementation of the HACCP system to evaluate the adequacy of the HACCP plan.

FSIS intends to begin verifying that small and very small establishments meet all validation requirements beginning on April 4, 2016.. Therefore, these establishments will have approximately ten months to gather all necessary in-plant demonstration documents before FSIS will verify and enforce the second element of validation.

Comment: Two commenters asked for information on who was going to verify establishments meet validation requirements. These commenters asked whether FSIS would "approve" establishments' validation documentation. One commenter also asked whether the Public Health Information System (PHIS) is programmed to have validation checks recorded.

Response: FSIS does not approve an establishment's validation records. FSIS verifies compliance with regulatory requirements. IPP, including EIAOs, verify that establishments meet validation requirements, and FSIS will be providing instructions for performing verification for both types of personnel. Inspectors will verify that establishments meet validation requirements during performance of the Hazard Analysis Verification (HAV) tasks, and EIAOs will do a more in-depth verification of establishment records to verify that establishments meet the validation requirement during food safety assessments. All Agency verification activities are documented in the PHIS system. Routine verification of validation occurs during performance of the HAV task, and findings related to validation are documented in PHIS as part of that task.

Comment: One commenter expressed concern that the validation guidance will unnecessarily increase the number

of non-compliance reports issued by FSIS inspection personnel.

Response: As explained in the May 2013 Federal Register notice, the guidance is meant for establishments and does not set new requirements. FSIS will ensure that IPP understand validation requirements and, as stated above, will issue necessary instructions to field personnel so that they are aware of the final guidance and share it with establishments. FSIS will also issue necessary instructions and training to field personnel for them to verify that establishments meet all validation requirements.

Next Steps

FSIS will implement the new verification activities in a phased approach based on establishment size. For large establishments, verification of the second element of validation will be delayed until January 4, 2016. For small and very small establishments, the Agency will delay implementation until April 4, 2016. After establishments have had time to collect the necessary in-plant validation data, IPP will verify that establishments meet validation requirements during HAV tasks, and EIAOs will do a more in-depth verification of establishment records to verify that

establishments meet validation requirements during food safety assessments.

Until FSIS begins enforcing all validation requirements, FSIS inspection personnel will continue to issue noncompliance records (NRs) if an establishment lacks the required scientific or technical support for its HACCP system, if the scientific or technical support is inadequate, or if the establishment's control measures (CCPs or prerequisite programs) do not incorporate the parameters described in the scientific support, and the establishment does not have data to support the technical adequacy of the control measures. FSIS will continue to issue a Notice of Intended Enforcement if, taken together with other relevant findings, an establishment's scientific or technical support is inadequate, and the Agency can support a determination that the establishment's HACCP system is inadequate for any of the reasons provided in 9 CFR 417.6.

Moreover, if, in conducting a Food Safety Assessment (FSA), an EIAO finds that an establishment has not collected in-plant data to demonstrate that its HACCP process works as intended, the EIAO will note this finding in the FSA and inform the establishment. Until FSIS begins enforcing the in-plant data requirements, FSIS will not

issue NRs or take enforcement actions based solely on a finding that an establishment lacks in-plant validation data.

USDA Non-Discrimination Statement

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U.S. Department of Agriculture

Director, Office of Adjudication

1400 Independence Avenue, SW

Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: program.intake@usda.gov

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Done at Washington, DC on: May 8, 2015.

Alfred V. Almanza,
Acting Administrator.

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